

1

2 "Valve"

3

4 The present invention relates to artificial cardiac
5 or heart valves, more particularly to flexible
6 leaflet heart valves which are used to replace
7 natural aortic or pulmonary valves of the heart.

8

9 Ideally artificial heart valves should work in a
10 similar fashion to natural heart valves in that when
11 blood flows in a particular direction the valve
12 adopts an open position to permit blood flow through
13 it, whereas when blood tries to flow in the opposite
14 direction the valve adopts a closed position
15 preventing the flow of blood in the reverse
16 direction through the valve (regurgitation).

17

18 Natural heart valves use thin flexible tissue
19 leaflets as the closing members. In the closed
20 position the leaflets are arranged such that each
21 leaflet contacts its neighbour. This arrangement
22 serves to close the valve and prevent the back flow

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1 of blood through the valve. In the open position
2 the leaflets separate from each other and move
3 radially towards the inner walls of the blood vessel
4 in which the valve is located. This open
5 configuration of the valve permits the flow of blood
6 through the valve.

7
8 A number of artificial cardiac valves have been
9 produced which comprise leaflets which open and
10 close in a similar fashion to natural valve
11 leaflets. However, although the artificial valves
12 work in a similar manner to the natural valves, the
13 geometries of the leaflets differ due to the
14 properties of the materials used in the construction
15 of the synthetic heart valves.

16
17 A number of factors have to be considered when
18 designing artificial heart valves of similar design
19 to natural heart valves. These include the pressure
20 gradient required to open and close the leaflets of
21 the valve, regurgitation, blood handling and
22 durability of the valve.

23
24 The leaflets of both natural and synthetic heart
25 valves must be capable of withstanding a high back
26 pressure across the valve when they are in the
27 closed position, yet be capable of opening with a
28 minimum of pressure across the valve in the forward
29 direction of blood flow.

30
31 This is necessary to ensure correct operation of the
32 valve even when blood flow is low. Further the

1 valve should open quickly and as wide as possible
2 when blood flows in the desired direction. The
3 maximum orifice of the valve in the open position is
4 generally dictated by the width of the valve.

5
6 In order to minimise closing regurgitation (reverse
7 blood flow through the closing valve) in the closed
8 position of the valve, the free edges of the
9 leaflets should come together to form a seal to
10 minimise the reverse flow of blood.

11
12 The valve design and the materials used for valve
13 construction should minimise the activation of both
14 the coagulation system and platelets. The flow of
15 blood through the valve should avoid exposing blood
16 to either regions of high shear or relative stasis.

17
18 Conventional heart valves typically comprise an
19 annular frame disposed perpendicular to the blood
20 flow. The annular frame generally has three posts
21 extending in the downstream direction defining three
22 generally U-Shaped openings or scallops between the
23 posts. The leaflets are attached to the frame
24 between the posts along the edges of the scallops
25 and are unattached at the free edges of the leaflets
26 adjacent to the downstream ends of the posts.

27
28 International Patent Application WO 98/32400
29 entitled "Heart Valve Prosthesis" discloses a
30 cardiac valve design, using closed leaflet geometry,
31 comprising essentially a trileaflet valve with
32 leaflets moulded in a geometry derived from a sphere

1 towards the free edge and a cone towards the base of
2 the leaflets. The spherical surface, defined by its
3 radius, is intended to provide a tight seal when the
4 leaflets are under back pressure, with ready opening
5 provided by the conical segment, defined by its
6 half-angle, at the base of the leaflets.

7
8 International Patent Application WO 01/41679
9 discloses a heart valve wherein the leaflets have
10 been designed to facilitate wash out of the whole
11 leaflet orifice including the area close to the
12 frame posts. This application teaches that stresses
13 are highest in the region of the commissures where
14 loads are transmitted to the stent, but they are
15 reduced when the belly of the leaflet is as low as
16 practicable in the closed valve. To ensure a belly
17 in the leaflet, the above application indicates that
18 there must be sufficient material in the leaflet.

19
20 In addition, in order to be suitable for
21 implantation, synthetic valves should be
22 sufficiently durable such that they are clinically
23 functional for at least 20 years. Durability of the
24 synthetic leaflets depends on the materials from
25 which the leaflets are constructed and also the
26 stresses to which the leaflets are subjected during
27 use. However, although improvements have been made
28 to cardiac valves over recent years, problems still
29 exist with artificial valves. Although several
30 materials have suitable hydrodynamic properties,
31 many valves constructed using materials with
32 apparently suitable hydrodynamic properties

1 nevertheless fail during use, due to fatigue caused
2 by the repeated stresses of cycling from a closed to
3 an open position.

4

5 The present inventor have surprisingly found that,
6 by using leaflets with parabolic configuration in
7 cross section, stresses of the leaflets can be
8 reduced and hence the lifespan of the valve may be
9 improved.

10

11 It is an aim of the present invention to provide an
12 improved cardiac valve prosthesis.

13

14 Thus, according to the present invention, there is
15 provided a cardiac valve prosthesis comprising:

16

17 a frame and at least two flexible leaflets;

18

19 wherein the frame comprises an annular portion
20 which, in use, is disposed substantially
21 perpendicular to the blood flow, the frame
22 having first and second ends, one of the ends
23 defining at least two scalloped edge portions
24 separated and defined by at least two posts,
25 each leaflet being attached to the frame along
26 a scalloped edge portion and being movable
27 between an open and a closed position,

28

29 each of the at least two leaflets having a
30 blood inlet side, a blood outlet side and at
31 least one free edge, the at least two leaflets
32 being in a closed position when fluid pressure

1 is applied to the outlet side such that the at
2 least one free edge of a first leaflet is urged
3 towards the at least one free edge of a second
4 or further leaflet, and the at least two
5 leaflets being in an open position when fluid
6 pressure is applied to the blood inlet side of
7 the at least two leaflets such that the at
8 least one free edge of the first leaflet is
9 urged away from the at least one free edge of
10 the second or further leaflet;

11
12 wherein, in a first plane perpendicular to the
13 blood flow axis, the length of each leaflet in
14 a circumferential direction (XY) between the
15 posts at any position along the longitudinal
16 axis (Z) of a post is defined by a parabolic
17 function.

18
19 It is understood that reference to a parabolic
20 function includes reference to any
21 pseudotrigonmetric, pseudoelliptical, smooth
22 function or table of values that describe a geometry
23 which is substantially parabolic.

24
25 The use of a pseudo function to describe a parabolic
26 function will be clear to one skilled in the art.

27
28 Preferably the parabolic function defining the
29 length of a leaflet in the circumferential direction
30 (XY) between the posts at any position along the
31 longitudinal axis (Z) of a post is defined by
32

$$Y_z = \left(\frac{4R}{L_z^2} \right) x \cdot (L_z - x)$$

2

3 Wherein Y_z = Y offset at a particular co-ordinate X
4 and Z

5 R = parabolic maximum

6 L_z = straight line distance between a
7 first post and a second post of the frame
8 at a height Z

9 x = distance from origin of post towards
10 another post

11

12 wherein the length of the parabola can be
13 determined by

14

$$15 \quad \text{Length} = \int_0^L \sqrt{1 + \left(\frac{dy}{dx} \right)^2} dx$$

16

17 Preferably at least one correction factor can be
18 applied to the measured lengths of for example L_z
19 or R to take into account changes in the dimensions
20 of the frame or material of the leaflet during the
21 cycling of the cardiac valve between an open and
22 closed position. For example, such changes, in the
23 dimensions may be, but are not limited to, inward
24 movement of the posts of the prosthesis on closure
25 of the valve, stretch in leaflet material on closure
26 of the valve, or movement in the notional point of
27 coincidence of the leaflets. It will be clear to
28 the skilled man how to determine the correction

1 factor required in view of the frame and leaflet
2 material selected.

3
4 Preferably the correction factor is positive,
5 negative or zero.

6
7 The materials chosen to form the frame and the
8 leaflets of the prosthesis and the design of the
9 frame will influence to what extent the prosthesis,
10 including both the frame and the leaflets, yields to
11 the forces to which the prosthesis is subjected
12 during valve closure and opening. For example,
13 typically, inward movement of the posts of the
14 prosthesis occurs on closure of the valve due to the
15 force of the backward flow of blood on the leaflet.
16 This typically occurs to a greater extent at the
17 tips of the posts than where the posts meet the
18 frame. A correction factor is preferably included
19 in the determination of the XY lengths of the
20 leaflet at each height in Z to compensate for this
21 movement in the frame.

22
23 Preferably the cardiac valve prosthesis of the first
24 aspect of the invention comprises three leaflets.

25
26 In an embodiment of the valve comprising three
27 leaflets, one end of the frame of the cardiac valve
28 prosthesis defines at least three scalloped edge
29 portions separated by at least three posts, wherein
30 each leaflet is attached to the frame along a
31 corresponding scalloped edge portion.

32

1 In such embodiments, preferably the three posts are
2 rotationally symmetrically distributed around the
3 circumference of the frame.

4
5 Preferably the frame is a collapsible stent. This
6 may be advantageous as a collapsible stent may be
7 delivered to a patient by percutaneous delivery. In
8 a preferred embodiment of the valve wherein the
9 frame is a collapsible stent, the collapsible stent
10 may be moved from a collapsed to an erect position
11 using an inflatable balloon when the stent is
12 suitably located in the patient.

13
14 The inventor has provided an improved cardiac valve
15 prosthesis by determining an advantageous leaflet
16 geometry. Indeed, a leaflet having such geometry
17 comprises an independent aspect of the present
18 invention.

19
20 According to a second aspect of the invention there
21 is provided a valve leaflet for use in the valve
22 according to the first aspect of the invention,
23 wherein the length of the leaflet in a
24 circumferential direction (XY) between the lateral
25 edges at any position along the lateral edge for
26 attachment to the post is defined by a parabolic
27 function.

28
29 Preferably the valve leaflet is a cardiac valve
30 leaflet for use in a cardiac valve prosthesis, more
31 preferably the cardiac valve prosthesis of the first
32 aspect of the invention.

1
2
3 As discussed above a parabolic function includes any
4 pseudotrigonometric, pseudoelliptical, smooth
5 function or table of values that describe a geometry
6 which is substantially parabolic.

7
8 Preferably the parabolic function defining the
9 length of a leaflet in the circumferential direction
10 (XY) between the posts at any position along the
11 longitudinal axis (Z) of a post is defined by
12

$$13 \quad Y_z = \left(\frac{4R}{L_z^2} \right) x \cdot (L_z - x)$$

14
15 Wherein Y_z = Y offset at a particular co-ordinate X
16 and Z
17 R = parabolic maximum
18 L_z = straight line distance between a
19 first post and a second post of the frame
20 at a height Z
21 x = distance from origin of post towards
22 another post
23

24 wherein the length of the parabola can be
25 determined by
26

$$27 \quad \text{Length} = \int_0^L \sqrt{1 + \left(\frac{dy}{dx} \right)^2} dx$$

28
29

1 Preferably at least one correction factor can be
2 applied to the measured lengths of for example L_z
3 or R to take into account changes in the dimensions
4 of the frame or material of the leaflet during the
5 cycling of the cardiac valve between an open and
6 closed position.

7
8 Preferably the correction factor is a positive,
9 negative or zero.

10
11 The leaflets are preferably formed from any
12 biostable and biocompatible material.

13
14 Preferably the leaflets are formed from Elasteon.

15
16 Preferably the leaflet has different thicknesses
17 along a cross section defined by the intersection of
18 a plane perpendicular to the blood flow axis.

19
20 More preferably the thickness of the cross section
21 of the leaflet in the XY plane, defined by the
22 intersection of a plane perpendicular to the blood
23 flow axis, changes gradually and substantially
24 continuously from a thickest portion where the
25 leaflet is conjoined to the frame to a thinnest
26 portion at the midpoint of the XY plane of the
27 leaflet.

28
29 The leaflets of a valve as described above have a
30 top and bottom. In a preferred embodiment, wherein
31 the valve is a cardiac valve prosthesis of the first
32 aspect of the invention, the bottom of the leaflet

1 is attached to the scalloped portion and the top of
2 the leaflet defines the free edge.

3
4 Preferably the free edge of the leaflet is shaped to
5 increase the length of the free edge of the leaflet
6 relative to the length of the leaflet in the XY
7 direction.

8
9 A valve leaflet of the second aspect of the
10 invention may be manufactured as part of the valve
11 prosthesis or may alternatively be formed
12 independently and then attached to the valve once
13 formed.

14
15 Typically changing the diameter of the valve or
16 height of the posts of the frame affects the
17 calculation of leaflet geometry i.e. the length of
18 the leaflets in the XY direction required to obtain
19 suitable closure of the valve. Conventionally,
20 geometric scaling is employed to determine the
21 leaflet geometry for different diameters of valves,
22 but this technique lacks accuracy.

23
24 An advantage of the parabolic function described
25 herein to determine the XY length of the leaflet of
26 a cardiac valve is that the function can be used
27 irrespective of valve diameter or the height of the
28 posts of the frame to determine suitable leaflet
29 geometry and do not require the use of geometric
30 scaling.

31

1 Therefore functions disclosed by the present
2 Application which describe length in the
3 circumferential direction (XY) of a leaflet e.g. the
4 leaflet geometry optimised for a 27mm inside
5 diameter of stent can be used to describe the length
6 in the circumferential direction (XY) leaflet
7 geometry for a stent of different diameter e.g. 17mm
8 inside diameter stent.

9
10 This makes the design and manufacture of valves of
11 different diameters which comprise the leaflets of
12 the second aspect of the invention more convenient.

13
14 Preferably the free edge of the leaflet is shaped
15 such that in the longitudinal direction (Z) the free
16 edge of at least one leaflet is parabolic.

17
18 The parabola can be in either direction. However if
19 the parabola extends away from the frame preferably
20 the maximum height of the parabola is 0µm to 500µm
21 more preferably 0µm to 100µm, even more preferably
22 0µm to 50µm higher than the notional straight line
23 between the ends of the parabola.

24
25 More preferably the free edge of at least one
26 leaflet is parabolic in the longitudinal direction
27 toward the scalloped edge portion of the frame such
28 that the maximum depth of the parabola is between
29 50µm to 1000µm, more preferably 50µm to 500µm, even
30 more preferably 50µm to 100µm lower than the

1 notional straight line between the ends of the
2 parabola.

3
4 The inventor has surprisingly shown that by making
5 the free edge of valve leaflets parabolic, the
6 stress and strain characteristics of the leaflet at
7 the free edge are improved.

8
9 In particular embodiments the parabolic shape of the
10 free edge may be produced by trimming of the free
11 edge.

12
13 The valve of the first aspect of the invention can
14 be manufactured by any suitable method as known in
15 the art for example by adapting the method as
16 disclosed in WO 01/41679 or WO 02/100301. During
17 manufacture of a cardiac valve prosthesis it is
18 preferable if the leaflets are cast in a shape which
19 minimises the stresses in the leaflet during cycling
20 of the valve between the open and closed position.
21 Preferably, the leaflets are formed in a neutral
22 position, not fully open or closed. In addition, as
23 will be appreciated by those skilled in the art, in
24 a fully closed position the free edge of the
25 leaflets will be touching or almost touching each
26 other making manufacture of the leaflet difficult.
27 Once the length in XY of the leaflet, in respect of
28 the frame at a height Z has been determined the cast
29 shape of the leaflet can be defined to allow
30 manufacture of the leaflet on a forming element.

31

1 A preferred method of manufacture of the leaflets of
2 the first aspect of the invention has been developed
3 by the inventor. Indeed this preferred method
4 provides a further independent aspect to the
5 invention.

6

7 According to a third aspect there is provided a
8 method of manufacturing a cardiac valve prosthesis
9 wherein the method comprises;

10

- 11 - providing a forming element having at least
- 12 two leaflet-forming surfaces wherein the
- 13 forming surfaces are such that the length in
- 14 the circumferential direction (XY) of the
- 15 leaflet-forming surface is defined by a
- 16 parabolic function,
- 17 - engaging the forming element with a frame,
- 18 - applying a coating over the frame and the
- 19 engaged forming element, the coating binding to
- 20 the frame, the coating over the leaflet-forming
- 21 surfaces forming at least two flexible
- 22 leaflets, the at least two flexible leaflets
- 23 having a length in the circumferential
- 24 direction (XY) defined by a parabolic function
- 25 and a surface contour such that when the first
- 26 leaflet is in a neutral position an
- 27 intersection of the first leaflet with at least
- 28 one plane perpendicular to the blood flow axis
- 29 forms a wave,
- 30 - disengaging the frame from the forming
- 31 element.

32

1 The coating is preferably a synthetic polymer
2 material, more preferably a synthetic resin or
3 plastics material.

4
5 As indicated above, when casting the leaflets, it is
6 desirable to keep the leaflets in a neutral position
7 and not touching each other. This is achievable by
8 casting the leaflets in a wave configuration. The
9 leaflets are in a neutral position intermediate to
10 the open and closed position in the absence of fluid
11 pressure being applied to the leaflets.

12
13 The shape of the leaflet forming surfaces on which
14 the leaflets are cast is preferably defined by a
15 wave function. The wave function is thus applied to
16 the leaflet(s) to aid production of the leaflets
17 whose length in an XY direction has been determined.

18
19 The shape of the leaflet forming surfaces on which
20 the leaflets are cast may be defined by a first wave
21 having a first frequency. The first wave may be a
22 sinusoidal wave.

23
24 Alternatively, the shape of the leaflet forming
25 surfaces on which the leaflets are cast may be
26 defined by at least two waves of differing
27 frequencies, which together form a composite wave.

28
29 A composite wave can be more complicated than a
30 single wave function. This provides a greater range
31 of leaflet cast shapes, wherein the XY lengths of
32 the leaflet at each height Z is defined by a

1 parabolic function or the like, in which the
2 leaflets may be manufactured.

3
4 Preferably the wave defining the leaflet forming
5 surfaces and thus the cast shape of a leaflet is
6 asymmetric about the vertical mid plane parallel to
7 and intersecting the blood flow axis of the leaflets
8 when in use.

9
10 Alternatively, the wave defining the leaflet forming
11 surfaces and thus the cast shape of a leaflet is
12 asymmetric about the vertical mid plane parallel to
13 and intersecting the blood flow axis of the
14 leaflets.

15
16 In preferred embodiments the method further
17 comprises trimming the free edge of at least one fo
18 the leaflets formed. In particularly preferred
19 embodiments the method further comprises trimming
20 the free edge to a parabolic shape.

21
22 It is preferred that the frame comprises three
23 posts. Preferably the number of leaflet forming
24 surfaces is equal to the number of posts.

25
26 In the method of the invention the coating may be
27 applied to the frame in any suitable way known in
28 the art, for example using dip moulding,
29 conventional injection moulding, reaction injection
30 moulding or compression moulding.

31

1 Dip moulding can be used to form surgical implants
2 of relatively complex shapes. Typically dip
3 moulding is achieved by dipping a forming element
4 into synthetic polymer material, which may include
5 polymer resin or plastic material, removing the
6 forming element from the synthetic polymer material
7 and allowing the resultant coating of synthetic
8 polymer material on the forming element to dry or
9 cure. The moulded article is then removed from the
10 forming element.

11
12 A disadvantage of conventional dip moulding, as
13 described above, is that during the moulding of
14 intricate shapes, bubbles of air frequently become
15 trapped in cavities or recesses of the mould
16 template. These bubbles of air remain trapped in
17 the moulded article when the article is cured and
18 give rise to holes or pits in the moulded article
19 rendering the moulded article unsuitable for use.
20 Another problem encountered is that of providing an
21 even coating for articles of complex geometry. For
22 example, precision coating is essential for
23 producing surgical implants of intricate shapes such
24 as prosthetic heart valves. In particular, the
25 problems of bubbles and applying an even coating are
26 encountered when more viscous moulding materials are
27 used for moulding.

28
29 These problems with dip moulding can be minimised by
30 using inverted dip moulding.

31

1 The coating may be applied over the frame by a
2 method of inverted dip moulding comprising the
3 steps:

- 4
- 5 - submerging a forming element in a moulding
 - 6 solution;
 - 7 - inverting said forming element whilst in the
 - 8 moulding solution; and
 - 9 - isolating the forming element from the
 - 10 moulding solution so that the coating thus
 - 11 formed on the forming element can be dried
 - 12 or cured.
- 13

14 Inversion of the forming element whilst in the
15 moulding solution reduces the number of bubbles
16 formed in the coating. Furthermore, such apparatus
17 enables more efficient use of moulding solution and
18 lends itself advantageously to batch processing.

19

20 In embodiments in which inverted dip moulding is
21 used, the method may comprise the steps of:

- 22 (i) attaching a forming element to a platform;
 - 23 (ii) sealing a housing to said platform to form a
 - 24 closed chamber;
 - 25 (iii) filling said closed chamber with moulding
 - 26 solution until the forming element is
 - 27 submerged;
 - 28 (iv) inverting said closed chamber;
 - 29 (v) isolating the coated forming element from
 - 30 the moulding solution.
- 31

1 The coated forming element can be isolated from the
2 moulding solution by either breaking the seal and
3 removing the platform, for example by raising the
4 platform and thus the forming element out of the
5 solution, or by draining the moulding solution from
6 the closed chamber via outlet means.

7

8 An apparatus for use in aspects of this invention in
9 which inverted dip moulding is used comprises:

10

- 11 - at least one platform adapted to hold at
12 least one forming element;
- 13 - at least one housing having an open end
14 adapted to fit over said at least one
15 forming element;
- 16 - sealing means for reversibly sealing said
17 housing to said platform to form a closed
18 chamber suitable for holding a moulding
19 solution;
- 20 - means for inverting said closed chamber;
- 21 - closeable inlet means for introducing a
22 moulding solution into the closed chamber;
23 and
- 24 - closeable outlet means for releasing a
25 moulding solution from the housing.

26

27 In particular embodiments of the manufacture of the
28 cardiac valve leaflet, in particular, coating of the
29 frame to form the leaflets, inverted dip moulding
30 and cutting or trimming of the leaflets, the forming
31 element is comprised of at least two portions

1 wherein portions are releasably attached to each
2 other.

3
4 Preferably releasable attachment of the at least two
5 portions of the forming element is provided by a
6 screw.

7
8 In a particular embodiment a first portion of the
9 forming element is a cardiac valve frame mounting
10 portion and a second portion is a base portion. The
11 base portion may be releasably attachable to the
12 inverted dip moulding apparatus.

13
14 The coating may be heated prior and / or during
15 moulding to aid movement of the material around the
16 forming element. This may be achieved by for
17 example heating at least a part of the moulding
18 apparatus is heated such that it heats the moulding
19 solution.

20
21 Preferably the synthetic polymer material is
22 biostable and biocompatible.

23
24 More preferably the synthetic polymer material is
25 Elasteon.

26
27 As described above, the inventor has found that
28 providing a parabolic shape to the free edge is
29 advantageous.

30
31 The parabolic shape may be formed during the coating
32 process or alternatively subsequent to manufacture

1 of the leaflets. It has been found that it may be
2 advantageous to cut the leaflets after formation.
3 For example, as discussed above, it may be
4 advantageous to trim the free edge of a leaflet,
5 e.g. to form a parabolic shape.

6
7 To date, conventional blades have been used to cut
8 moulded devices such as cardiac valves and leaflets
9 formed from synthetic polymer material. However,
10 these conventional blades become blunted over a
11 relatively short period of time, leading to the
12 production of moulded devices with a poor surface
13 finish on the cut edge.

14
15 To provide a high quality finish to a cut edge of
16 the leaflet with minimal disruptions to the cutting
17 process to replace cutting blades it has been
18 determined that an ultrasonic cutting device may be
19 used.

20
21 The leaflets may be cut using an ultrasonic cutting
22 device comprising

- 23 (i) an ultrasonic transducer;
- 24 (ii) an elongate blade; and
- 25 (iii) attachment means to enable detachable
26 attachment of the blade to the transducer so
27 that, in operation, the transducer causes
28 the blade to vibrate in a direction along
29 the longitudinal axis of the blade.

30
31 It has been found that, for a given ultrasonic
32 frequency, by altering the dimensions of an elongate

1 blade, optimal operation of the cutting device can
2 be achieved. Reducing the amplitude of vibrations
3 perpendicular to the plane of the blade results in a
4 cleaner cut. It has been found that by having a
5 blade of this particular construction precise
6 cutting of synthetic polymer material, for example,
7 resin and plastics materials can be achieved. The
8 cutting device of the present invention is
9 particularly suitable for cutting acetyls,
10 polyurethane and polymeric materials.

11
12 Preferably the blade has a width to length ratio of
13 between 0.1 to 0.4. By width means the width of the
14 widest part of the blade and by length is meant the
15 length of the longest part of the blade.

16
17 Preferably the elongate blade has a length in the
18 range of 20 to 30 mm, a thickness in the range of
19 0.5 to 2 mm and a width in the range of 2 to 10 mm.
20 More preferably the width of the blade is between 5
21 and 8 mm.

22
23 Preferably the ultrasonic transducer or motor
24 produces vibrational energy at a frequency of 15 Hz.

25
26 The blade is provided with a terminal end, which is
27 the end furthest away from the transducer, which
28 terminal end may have a single cutting edge and this
29 may be rounded in shape. Preferably the blade has a
30 plurality of cutting edges. Preferably the blade
31 has cutting edges along its longitudinal sides which
32 form a point at the terminal end of the blade, for

1 example in an arrowhead configuration. Preferably,
2 the longitudinal sides are arcuate in shape. In one
3 embodiment the blade is needle-shaped. Preferably
4 the blade is symmetrical in shape about its
5 longitudinal axis.

6
7 The blade may be constructed from any suitable
8 material such as stainless steel, mild steel or
9 ceramic material. Preferably the blade is
10 constructed from a ceramic material. This is
11 advantageous as ceramic material is harder than
12 steel and remains cooler during operation of the
13 cutting device as there is less heat transfer to the
14 blade.

15
16 Preferably the cutting apparatus further comprises
17 (i) a stylus for guiding the blade of the
18 cutting device on the surface of the article
19 to be cut which stylus comprises a rotatable
20 ball bearing mounted on an arm; and
21 (ii) attachment means for attaching the stylus to
22 the ultrasonic cutting device.

23
24 The stylus is positioned so that, in operation, the
25 ball bearing is in contact with the surface of the
26 article to be cut. Preferably the rotatable ball
27 bearing is positioned above, but not in contact
28 with, the terminal end of the blade. Preferably the
29 outer most part of the rotatable ball bearing does
30 not extend to the outermost tip of the terminal end
31 of the blade so that, while the ball bearing is in
32 contact with the article to be cut, the cutting edge

1 of the terminal end of the blade penetrates the
2 article by a constant predetermined amount. This
3 results in a consistent and precise cut with each
4 part of the article experiencing the same exposure
5 to the cutting edge of the blade.

6
7 The attachment means for attaching the stylus to the
8 ultrasonic cutting device may form part of means for
9 mounting the cutting device on a mounting table. The
10 means for mounting the cutting device on a mounting
11 table may further comprise means such as a 3-axis
12 drive unit as known in the art in which each arm of
13 the drive unit can move linearly in three directions
14 perpendicular to each other such that the ultrasonic
15 cutting device can be suitably positioned relative
16 to the article to be cut.

17
18 Preferably the article to be cut is mountable on the
19 drive unit, for example the forming element on which
20 the cardiac valve leaflet to be cut is formed may be
21 mountable on the drive unit.

22
23 A cardiac valve leaflet may be cut using an
24 ultrasonic vibrating blade comprising the steps of,
25 (i) positioning a blade relative to the heart
26 valve leaflet to be cut;
27 (ii) vibrating the blade;
28 (iii) moving the heart valve leaflet to be cut
29 relative to the vibrating blade or
30 alternatively moving the vibrating blade
31 relative to the heart valve leaflet to be

1 cut so that the blade cuts the heart valve
2 leaflet to the required shape.

3
4 The heart valve leaflet may be mountable on the
5 mounting table while it is on the forming element on
6 which it was moulded.

7
8 As described herein, an advantage of the valve of
9 the first aspect of the invention is that stresses
10 experienced by the leaflets during the cycling from
11 the closed to the open positions are minimised.

12
13 By minimising the stresses present in the leaflets
14 of the valve during cycling from the closed to the
15 open position and back to the closed position the
16 lifetime of the synthetic leaflets is likely to be
17 increased.

18
19 The present inventor has determined that fatigue
20 failures of previous synthetic valve are due to
21 bending stresses. In particular, the inventor has
22 determined that bending stresses affect synthetic
23 polymer valve material differently to non-synthetic
24 valve material.

25
26 Indeed, the present inventor has determined that by
27 considering the stresses and strains of the leaflets
28 during cycling of the valve an optimal leaflet
29 geometry can be determined. This principle may be
30 applied to the design of other valves.

31

1 Accordingly, in a further independent aspect of the
2 invention there is provided a method of designing a
3 cardiac valve prosthesis comprising the steps,

4

5 a) providing a model of a heart valve
6 comprising a frame and at least two flexible
7 leaflets,

8

9 b) generating loads experienced by at least one
10 cardiac valve leaflet in use and applying these
11 to the model,

12

13 c) determining the stress distribution of the
14 leaflet,

15

16 d) changing the circumferential length of the
17 leaflet in XY for any position in Z,

18

19 e) determining the new stress distribution of
20 the leaflet,

21

22 f) repeating steps D and E to minimise local
23 stress concentrations in the leaflet.

24

25 In preferred embodiments of this aspect of the
26 invention, the cardiac valve prosthesis is a cardiac
27 valve prosthesis of a first aspect of the invention.

28

29 In a particularly preferred embodiment the model
30 comprises three flexible leaflets.

31

1 Preferably the method further includes the step of
2 adjusting the model to account for factors which
3 influence the stress distribution of the leaflet
4 during the cycling of the cardiac valve between an
5 open and closed position.

6
7 More preferably, where the leaflets are formed from
8 synthetic polymer material, the method further
9 includes the step of adjusting the model to account
10 for factors depending on the synthetic polymer
11 material of the leaflet which influence the stress
12 distribution of the leaflet during the cycling of
13 the cardiac valve between an open and closed
14 position.

15
16 Preferably the length of the leaflet in the
17 circumferential direction (XY) between the posts at
18 any position along the longitudinal axis (Z) of a
19 post is defined by a parabolic function and at least
20 one correction factor. Preferably the correction
21 factor is used to compensate for at least one of,
22 but not limited to; inward movement of the posts of
23 the prosthesis on closure of the valve, stretch in
24 leaflet material on closure of the valve, or
25 movement in the notional point of coincidence of the
26 leaflets.

27
28 Such correction factors are advantageous as they
29 allow the determination of the XY length of the
30 leaflet to take into account factors which effect
31 the XY length of the leaflets required for closure
32 of the valve. For example, inward movement of the

1 posts of the prosthesis occurs on closure of the
2 valve, due to the force of the backward flow of
3 blood on the leaflet. This typically occurs to a
4 greater extent at the tips of the posts than where
5 the posts meet the frame. By providing a correction
6 factor in the determination of the XY lengths of the
7 leaflet at each height in Z to compensate for this
8 movement the leaflet length can be determined to
9 minimise bending stresses, in particular buckling of
10 the leaflet.

11

12 The free edge of the leaflet of the cardiac valve is
13 particularly subject to stress and strain.

14

15 Preferably the method further comprises the step of
16 providing different shapes and lengths of the free
17 edge of a leaflet.

18

19 This is advantageous as it enables the effect of
20 trimming the leaflet to particular shapes, for
21 example parabolic, to be determined.

22

23 Preferred aspects of the invention apply to each of
24 the other aspects mutatis mutandis.

25

26 An embodiment of the present invention will now be
27 described, by way of example only with reference to
28 the accompanying drawings wherein;

29

30 Figure 1a is a plan view of a trileaflet heart
31 valve in the closed position;

32

1 Figures 1b, 1c and 1d show plan views of heart
2 valves with 3, 4 or 5 posts in which full
3 closure of the valve is achieved;
4
5 Figures 1e, 1f and 1g show plan views of 3, 4
6 and 5 posted heart valves in which the length
7 XY of the free edge of the leaflets is defined
8 by a parabolic function;
9
10 Figure 2a is a perspective view of an
11 embodiment of a trileaflet heart valve of the
12 present invention in a semi-closed position;
13
14 Figure 2b is a perspective view of a prior art
15 trileaflet heart valve in a semi-closed
16 position;
17
18 Figure 3 is a plan view of an embodiment of a
19 trileaflet heart valve of the present invention
20 in a semi-closed position;
21
22 Figure 4a is a plan view of a prior art
23 trileaflet heart valve in a fully open
24 position;
25
26 Figure 4b is a plan view of a prior art
27 trileaflet heart valve as shown in figure 4a in
28 a fully closed position;
29
30 Figure 4c is a plan view of an embodiment of a
31 trileaflet heart valve according to the present
32 invention in a fully open position;

1
2 Figure 4d is a plan view of an embodiment of a
3 trileaflet heart valve according to the present
4 invention as shown in figure 4c in a fully
5 closed position;

6
7 Figure 5a is a cross section of the valve as
8 shown in figure 2a along line 3-3;

9
10 Figure 5b is a cross section of the prior art
11 valve as shown in figure 2b along line 3-3;

12
13 Figure 5c is a cross section of a valve with a
14 sigmoidal shaped leaflet in Z;

15
16 Figure 6 is a plan view illustration of an
17 embodiment of a trileaflet heart valve of the
18 present invention;

19
20 Figure 7a shows a partial cross section of a
21 post of an embodiment of a trileaflet heart
22 valve of the present invention in the open
23 position (II) and the closed position (I) of
24 the valve;

25
26 Figure 7b shows a partial cross section of an
27 embodiment of a leaflet of the present
28 invention along the vertical midplane in the
29 open position (II) and closed position (I) of
30 the valve;

31

1 Figure 7c shows a partial cross section of a
2 post of a prior art valve in the open position
3 (II) and closed position (I) of the valve;
4
5 Figure 7d shows a partial cross section of a
6 leaflet of a prior art valve along the vertical
7 midplane in the open (II) and closed (I)
8 position of the valve;
9
10 Figure 8a shows the principal stress envelope
11 present in a prior art heart valve leaflet;
12
13 Figure 8b shows the strain energy release
14 present in a prior art heart valve leaflet in
15 the X axis from a closed to open position;
16
17 Figure 8c shows the strain energy release
18 present in a prior art heart valve leaflet in
19 the Y axis from a closed to open position;
20
21 Figure 8d shows the resultant strain energy
22 release present in a prior art heart valve
23 during cycling from a closed to open position;
24
25 Figure 9a shows the principal stress envelope
26 present in an embodiment of a heart valve
27 according to the present invention;
28
29 Figure 9b shows the strain energy release
30 present in an embodiment of a heart valve
31 according to the present invention in the X
32 axis from a closed to open position;

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Figure 9c shows the strain energy release present in an embodiment of a heart valve leaflet according to the present invention in the Y axis from a closed to open position;

Figure 9d shows the resultant strain energy release present in an embodiment of a heart valve leaflet according to the present invention during cycling from a closed to open position;

Figure 10 is an illustration of an embodiment of one leaflet according to the present invention;

Figure 11 is a diagrammatic representation of a prior art leaflet moving from a semi-closed (a) to successively more open position (b) and (c) to a fully open position (d) illustrating the formation of a bubble or buckle;

Figure 12 illustrates a shape of the leaflet being defined by a first wave further to determination of the circumferential length of the leaflet;

Figure 13 is a graph of Cardiac Output (l/min) against mean Pressure Gradient (mmHg);

1
2 Figure 14a shows a sectional view of an
3 inverted dipping apparatus prior to moulding;
4
5 Figure 14b shows a sectional view of an
6 inverted dip moulding apparatus post moulding;
7
8 Figure 14c shows a cross sectional view of a
9 forming element suitable for use in the
10 moulding apparatus of the present invention;
11
12 Figure 15 is a perspective view of an
13 ultrasonic cutting device mounted on a mounting
14 table;
15
16 Figure 16 is a view of the cutting apparatus of
17 an ultrasonic cutting device;
18
19 Figure 17 is a perspective view of an
20 ultrasonic cutting apparatus according without
21 a stylus; and
22
23 Figure 18 is a side view of ultrasonic cutting
24 apparatus without a stylus.
25
26 As previously discussed, a number of designs have
27 been suggested for use in cardiac heart valves to
28 ensure that the heart valves have sufficient leaflet
29 material such that the valve is capable of opening
30 as wide as possible to the maximum orifice of the
31 valve, and that such opening requires as little

1 energy as possible and further that regurgitation of
2 blood through the valve is minimised.

3

4 In order to minimise the regurgitation of blood it
5 has been suggested that the free edge of the valve
6 is spherical in geometry to ensure that the free
7 leaflet edges are able to come together and seal
8 against one another.

9

10 US Patent 5,500,016 discloses a leaflet defined by
11 the equation:

12

13
$$z^2 + y^2 = 2RL(x-g) - \alpha(x-g)^2$$

14

15 to describe the geometry of the leaflets. As Z,
16 defines the shape of the leaflet in the blood flow
17 axis and as Z is defined as z^2 then a leaflet
18 defined by the above would have a spherical geometry
19 in the axis parallel to blood flow. International
20 Patent Application WO 98/32400 discloses that
21 spherical surfaces at the leaflet edges seal more
22 effectively than planar or conical surfaces.

23 International Application WO 01/41679 discloses that
24 stresses are highest in the region of the commissures
25 where loads are transmitted to the stent, but they
26 are reduced when the belly of the leaflet is as low
27 as practicable in the closed valve.

28

29 In addition, International Application WO 98/32400
30 also suggests that it is advantageous to provide a
31 spherical portion of leaflet adjacent to the base of
32 the leaflet as it confers advantages in the stress

1 distribution when the valve is closed and pressure
2 is greater downstream than upstream.

3
4 Thus, the prior art teaches that leaflets of heart
5 valves should have considerable excess material in
6 the vertical axis Z, parallel to the blood flow to
7 enable a suitable seal to be achieved at the free
8 edge of the leaflet and to reduce the stress present
9 in the leaflet during open and closing.

10
11 As shown in figure 1b, 1c and 1d, the use of a frame
12 comprising 3, 4 or 5 posts induces different angles
13 θ in the valve leaflets, to ensure a close fitting
14 tight seal of the leaflets, which minimises
15 regurgitation of blood through the valve. As the
16 number of posts increases, the smaller the angle θ
17 and the more bent the leaflets are at a particular
18 point. In cycling between the open and closed
19 position, the valve will undergo considerable
20 flexing, particularly at angle θ . The smaller the
21 angle θ , the greater the stress experienced by the
22 valve at this point and the more the likely the
23 valve is to fail due to stress.

24
25 The material properties of tissue, which has low
26 stress at low and moderate strain means tissue
27 valves are more able to cope with such flexing than
28 synthetic materials. Synthetic materials typically
29 have different stress to strain relationships than
30 tissue and higher stress is typically experienced by
31 these materials at low and moderate strains. This
32 means that flexing is more likely to cause damage to

1 leaflets constructed from synthetic material than
2 tissue material.

3
4 Previous valve designs have been largely based on
5 tissue valves and have not taken account of the
6 different material properties of synthetic material,
7 particularly synthetic polymer material.

8
9 In contrast to previous designs and teaching
10 concerning valve construction, which was driven by
11 the supposed need to obtain a close fitting seal of
12 the leaflets, particularly at the free edge, the
13 leaflets of the valves of the present invention were
14 designed to minimise the stress experienced by the
15 leaflet during cycling between the open and closed
16 position.

17
18 To reduce the sharp curvature, which promotes stress
19 points at specific points along the free edge, the
20 length of the free edge (XY) of the leaflet was
21 determined using a parabolic function. The
22 parabolic length of the free edge can be determined
23 by using the distances between the posts of the
24 frame where the free edge is conjoined to the posts
25 and the parabolic maximum.

26
27 As shown in figures 1e, 1f and 1g the use of a
28 parabolic shape at the free edge results in a
29 gentler curvature of the leaflets and enables the
30 length of the material along the free edge to be
31 determined from a knowledge of the frame dimensions.
32 However, this design, contrary to previous teaching,

1 does not necessarily allow close fitting to be
2 achieved between the leaflets at all points along
3 the free edge. However, surprisingly, the seal
4 obtained between the leaflets using a parabolic or
5 like function was found to be sufficient to minimise
6 regurgitation of blood through the valve to the
7 required degree for the valve to be effective.

8
9 The determination of the length XY at the free edge
10 of the leaflet is important to ensure that closure
11 of the leaflets is achieved and to minimise the
12 excess material of the leaflets at the free edge
13 such that the free edges of the leaflets do not fold
14 over each other in the closed position.

15
16 In addition to allowing determination of the length
17 of XY at the free edge of the valve, the present
18 Application also allows determination of the XY
19 lengths of the leaflets at all points in Z by using
20 a parabolic function to determine the shape of the
21 leaflets at all points in Z.

22
23 As shown in figures 5a, 5b and 5c, in the closed
24 position, the leaflet can be substantially linear
25 (figure 5a), have excess material such that a belly
26 forms (figure 5b) or have reduced XY lengths of the
27 leaflet towards the base such that the leaflet forms
28 a generally sigmoidal shape (figure 5c). In both
29 figures 5b and 5c the XY lengths of the leaflet and
30 thus the leaflet shape would be determined using a
31 non-continuous function.

32

1 The inventor has determined the belly in the valve
2 as shown in figure 5b would create increased stress
3 in the belly region. Further, it has been deterimed
4 that, as illustrated in figure 5c, a reduction of
5 material in XY towards the base of the posts
6 promotes an increase in the stress concentration at
7 the portion of the leaflets towards the free edge.

8
9 By determining the lengths XY of the leaflet as a
10 parabolic function or the like at each point in Z,
11 such that the XY lengths in Z vary as a continuous
12 function, localised stress concentrations can be
13 minimised and a more uniform stress distribution
14 across the leaflet achieved.

15
16 As shown in figure 1a and figure 2a, a preferred
17 embodiment of the heart valve prosthesis 8 of the
18 present invention comprises a stent or frame 10
19 which is substantially cylindrical. The frame has a
20 first end 12 and second end 14. The first end 12
21 comprises three scalloped edge portions 16a, 16b and
22 16c separated by three posts 18, each post having a
23 tip 20. The cardiac valve further comprises three
24 leaflets 30. Each leaflet 30 has a fixed edge 32
25 joined to a respective scalloped edge 16a, 16b or
26 16c of the frame 10 and a free edge 34 which extends
27 substantially between the tips 20 of the posts 18.

28
29 The leaflets 30 are configured to be movable from an
30 open to a closed position and from a closed to open
31 position. In an aortic position (when the
32 prosthesis is positioned at the site of the aortic

1 valve), the leaflets 30 have a blood inlet side 36
2 and a blood outlet side 38 and are in the closed
3 position when fluid pressure is applied to the
4 outlet side 38 i.e. by the blood of the aortic
5 artery and in the open position when fluid pressure
6 is applied to the inlet side 36 i.e. by the blood of
7 the ventricle. The leaflets are in a neutral
8 position intermediate to the open and closed
9 position in the absence of fluid pressure being
10 applied to the leaflets.

11

12 Where the valve is being used in a mitral position,
13 between the left atrium and left ventricle of the
14 heart, the orientation of the valve is opposite to
15 that described above such that blood flow from the
16 left atrium moves the leaflets to an open position,
17 the leaflets opening towards the left ventricle to
18 allow blood to flow into the left ventricle. Back
19 pressure from blood flow from the left ventricle
20 towards the left atrium causes the mitral valve to
21 close to minimise regurgitation.

22

23 In figure 5b which is a sectional view along line 3-
24 3 illustrating the closed position of a leaflet of a
25 valve of the prior art, a 'belly' portion 40 exists
26 in the mid portion of the leaflet. This 'belly'
27 portion between the free edge and the central
28 portion of the leaflet causes leaflets of the prior
29 art to have a double curvature, a curve in XY and a
30 curve in Z. Further, the 'belly' shape 40 causes
31 leaflets of the prior art to be almost concave in

1 shape when viewed in cross section along the
2 vertical midplane of the leaflet.

3
4 As shown in figure 5a, which is a sectional view of
5 the valve of the present invention along line 3-3 as
6 shown in figure 2a, no 'belly' is present in the
7 leaflets and in Z the leaflet in the closed position
8 is substantially linear.

9
10 The conventional design including a 'belly' portion
11 was previously favoured as it was thought to
12 maximise sealing of the valve at the free edge and
13 minimise regurgitation.

14
15 However, the double curvature, which comprises
16 curvature in XY plane and in Z plane results in
17 excess leaflet material at both the open and closed
18 position which promotes the formation of a bubble or
19 buckle 50 in the leaflet material (as shown in
20 figure 11) during movement from a closed to open
21 position.

22
23 This excess material is shown most clearly by
24 comparing figure 7d which shows a cross section of
25 the valve along the vertical midplane (line I-I of
26 figure 2b) of the leaflet 30 parallel to the blood
27 flow axis in a prior art leaflet with figure 7b
28 which shows a cross section along the vertical
29 midplane (line I-I of figure 2a) of a leaflet of the
30 present invention. This comparison clearly shows
31 that the leaflet 30 of the valve of the present
32 invention does not display a belly region 40.

1 Indeed the cross section shown in figure 7b
2 indicates that the leaflet shape of the present
3 invention is substantially linear in the vertical
4 direction in both the open and closed valve
5 positions.

6
7 To determine the circumferential length of material
8 in XY to remove the 'belly' 40 observed in prior art
9 leaflets, the length in the circumferential
10 direction (XY) of the leaflet for any position in z
11 must be determined, which still allows suitable
12 opening and closure of the valve.

13
14 As shown in figure 6 the material of the leaflet
15 must extend between the posts 18 such that in a
16 closed position the free edge of the leaflets 34
17 come together at point 42 to minimise regurgitation
18 of blood through the valve.

19
20 This circumferential length (XY) can be
21 mathematically defined using a parabolic function.

22
23 Function of a parabola

24
$$Y_z = \left(\frac{4R}{L_z^2} \right) x \cdot (L_z - x)$$

25
26 Wherein Y_z = Y offset at a particular co-ordinate X
27 and Z
28 R = parabolic maximum
29 L_z = straight line distance between a
30 first post and a second post of the frame
31 at a height Z

1 X = distance from origin of post towards
2 another post

3
4 To calculate the circumferential length (XY) at a
5 height point of the posts for a leaflet defined in
6 the circumferential (XY) direction by a parabolic
7 function the following function can be used:
8

9 length of parabolic curve = $\int_0^l \sqrt{1 + \left(\frac{dy}{dx}\right)^2} dx$

10
11 This allows a circumferential length (XY) to be
12 determined at each height point in Z.

13
14 Thus as shown in figure 10 the circumferential
15 length (XY) can be determined at Z1, Z2, Z3 ...Zn.

16
17 The length of the leaflet in the circumferential
18 direction (XY) is calculated and repeated in the
19 radial direction (Z) to provide the complete
20 geometry of the leaflet.

21
22 As the dimensions of the scallop edge 32 of the
23 frame 10 as defined by the posts 18 of the frame can
24 be determined by measuring the frame, then the
25 straight line distance between a first post and a
26 second post of the frame at a height Z (L_z) for a
27 leaflet 30 can be determined by measuring the
28 distance between the two posts 18 at several height
29 points in Z (where Z is a particular height along
30 the posts). This post to post distance can then be

1 used in the equation detailed above to generate a
2 parabola (P) at each height point. In the
3 embodiment shown, due to the scallop shape 32
4 defined by the posts 18 the circumferential length
5 of the leaflet in XY will decrease moving from the
6 first end at the tip 20 of the posts toward the
7 second end of the frame 14 at the base of the posts.
8 The more height points which are chosen, the more
9 lengths (P) which can be calculated along Z. If a
10 large number of height points are chosen the lengths
11 determined by the parabolic function moving from the
12 tip of the posts to the base will vary in a
13 substantially linear fashion.

14
15 The leaflets 30 of a valve 8 which are of
16 circumferential length (XY) as determined using the
17 above parabolic function will meet at the free edge
18 34 of the leaflet 30, but will not meet
19 significantly at points lower than the free edge 34.
20 The meeting of the leaflets at the free edge allows
21 regurgitation to be minimised without including
22 excess material or a belly region 40 in the leaflets
23 30.

24
25 The circumferential length (XY) can be further
26 adjusted to take account of factors which occur
27 during cycling of the heart valve. These factors
28 include inward movement of the posts 18 of the frame
29 10 due to pressure on the leaflets 30 during closing
30 of the valve. The amount of inward movement of the
31 posts 18 of the frame 10 is influenced by the
32 rigidity of the frame 10 and the pressure exerted on

1 the valve. The tips 20 of the posts 18 of the frame
2 10 move to a greater extent than the base of the
3 posts and as the scallop geometry between the posts
4 18 of the frame 10 is accurately known this
5 differential movement can be taken into account when
6 determining the optimal circumferential length (P)
7 of XY in the leaflet 30.

8
9 In addition to the posts 18 of the frame 10 moving
10 toward each other during closure, the posts 18 also
11 move towards the centre point 42 where the leaflets
12 meet or the point of coincidence. The
13 circumferential length XY of the leaflet can be
14 adjusted to account for this movement.

15
16 The material of the leaflet 30 typically has some
17 degree of elasticity and will stretch in response to
18 blood flow pressure. This stretching can again be
19 taken into account in determining the lengths of the
20 leaflet 30 to ensure that a belly region 40 of the
21 valve is minimised.

22
23 As shown in figure 8a, analysis of the stresses over
24 time incurred by heart valves during the cycling
25 process has revealed that the principal area of
26 stress 60 in existing cardiac valves is found close
27 to the midpoint of the free edge of the leaflets.

28
29 Using the data from figure 8a, strain energy release
30 in X and Y, as shown in figures 8b and 8c
31 respectively can be determined. Figure 8b shows
32 that leaflets of the prior art have a vertical

1 predisposition to defect propagation 62 at the free
2 edge 34. Figure 8c indicates that leaflets have a
3 predisposition to defect in the lateral dimension,
4 at an area 64 in the leaflet 30 lower than the free
5 edge of the leaflet 34, the lower area being located
6 above the central portion of the leaflet. In tests
7 during cycling of cardiac valves it has been found
8 that over time, the stress in this lower area
9 promotes failure of defects in the material to
10 occur. These defects can cause valve failure.

11
12 The present invention has shown that analysis of the
13 dynamics of existing valves during the cycling
14 process has determined that the stress in this lower
15 area is caused by the leaflets requiring to change
16 the direction of their surface curvature during
17 cycling.

18
19 In particular, as shown in figure 11, on cycling
20 from a closed to an open position a region lower
21 than the free edge forms a bubble like formation or
22 buckle 50 on the surface of the leaflet which is
23 opposite in direction to the curvature of the
24 surface of the rest of the leaflet.

25
26 On moving from the closed to open position, the
27 bubble like formation 50 is forced to become
28 inverted such that it projects in an opposite
29 direction causing a whip like action in the leaflet
30 30. This whip like action promotes high stresses in
31 the area lower than the free edge 34 of the leaflet,
32 as shown in figures 8a, 8b, 8c and 8d.

1
2 The inventor has surprisingly determined, as shown
3 in figure 9a, that the principal stress envelope in
4 relation to the valve as described in the present
5 application, wherein the circumferential length XY
6 of the leaflet at any point in Z is defined as a
7 parabolic function, is decreased across the whole of
8 the valve. In particular strain energy release in X
9 and Y, as shown in figures 9b and 9c respectively,
10 in relation to the valve of the present invention
11 indicates that a leaflet wherein the circumferential
12 lengths XY are determined by a parabolic function
13 has minimised predisposition to defect propagation
14 in the lateral dimension at an area in the leaflet
15 lower than the free edge of the leaflet and above
16 the central portion.

17
18 A reduction in the predisposition to defect
19 propagation in the lateral dimension at an area in
20 the leaflet between the free edge of the leaflet and
21 the central portion in the leaflet of the present
22 invention is observed because there is less excess
23 material and thus minimal belly in the leaflet of
24 the present design.

25
26 On moving from the closed to open position a bubble
27 like formation 50 is no longer created and thus a
28 whip like action does not occur in the leaflet. As
29 discussed, it is this whip like action which has
30 been determined to promote high stresses in the area
31 lower than the free edge of the leaflet. As
32 illustrated by comparing figures 8a and 9a, in

1 contrast to the valves of the prior art, uniform
2 principle stress distribution, is observed across
3 the surface of the leaflet of the valve described in
4 the present Application.

5
6 Minimisation of the regions of stress in the
7 leaflet, during cycling of the leaflet, will
8 increase the durability of the leaflet.

9
10 Use of a parabolic function to determine the
11 circumferential lengths XY of the leaflet at each
12 height point in Z causes the vertical distribution
13 of lengths of the leaflet to be substantially linear
14 at the fully open and closed position.

15
16 As described above, it will be appreciated by those
17 in the art that other functions with the addition of
18 suitable modifying factors could be used to derive a
19 function which substantially describes a parabola
20 and which leads to the vertical distribution of
21 lengths of the leaflet to be substantially linear at
22 the fully open and closed position, but which is
23 based on for instance an elliptical function.

24
25 As discussed, additional parameters may be included
26 in the parabolic function used to determine the
27 circumferential lengths XY of the leaflet. These
28 additional factors may account for movement in the
29 posts of the stent, elasticity of the leaflet
30 material during movement of the leaflets from a
31 closed to an open position or other factors which

1 occur during cycling which influence the length of
2 the leaflet require to allow closure.

3
4 The function described above explicitly determines
5 lateral lengths of the parabolic curve at any height
6 point in Z which is along a post of the frame. In
7 view of this the above function can be applied to
8 any diameter of valve or valves with different
9 heights of posts, without the need for geometric
10 scaling. This means that different dimensions of
11 valves can be manufactured with the same leaflet
12 geometry without further undue experimentation.

13
14 The surface contour of the leaflets 30 of the
15 embodiment described are such that in a fully open
16 position, the intersection of the leaflets of the
17 valve perpendicular to the blood flow axis, forms a
18 substantially cylindrical shape.

19
20 In addition to the above, it has also been
21 determined that stress at the free edge of the
22 leaflet, as shown in figure 8a, can be further
23 reduced by trimming the free edge 34 of the leaflet
24 in the longitudinal direction (Z) such that the free
25 edge is substantially parabolic 70, with the maximum
26 depth of the parabola being furthest from the
27 notional untrimmed free edge 74. The maximum depth
28 of the parabola is generally located at the midpoint
29 of the free edge 72 (figure 9a). Figure 9a shows
30 the effect of introducing a parabolic curve in the
31 vertical direction of the free edge. Comparison of
32 figures 8b, 8c and 8d with 9b, 9c and 9d shows that

1 the strain energy release at the free edge is
2 significantly reduced through the introduction of
3 the parabola in the longitudinal direction (Z).

4
5 Ideally the notional free edge 74 is trimmed in a
6 parabolic curve, wherein the maximum depth 72 of the
7 parabola 70 in the longitudinal direction toward the
8 second end of the frame is between 50 μ m to 1000 μ m,
9 more preferably 50 μ m to 500 μ m, even more preferably
10 50 μ m to 100 μ m lower than the notional straight line
11 74 between the ends of the parabola.

12
13 A different shape of cut, trim or notch can be
14 introduced in the free edge to decrease the stress
15 at the free edge. However, particular shapes of
16 cuts, trims or notches may introduce defects into
17 the leaflet which would decrease the leaflets
18 durability to stress. A parabolic trim as described
19 is therefore advantageous in that focal points of
20 stress are not introduced to the free edge of the
21 leaflet. Cuts, trims and notches which do not
22 create bending stresses at localised points on the
23 free edge are preferable.

24
25 In one embodiment a parabolic cut may be made using
26 an ultrasonic cutting device. As shown in figure 1,
27 in one embodiment the ultrasonic cutting device
28 comprises an ultrasonic transducer (100); a blade
29 (110); and attachment means (120) to enable
30 detachable attachment of the cutting blade to the
31 transducer. The blade has two arcuate cutting edges

1 which meet at a point to form the terminal end of
2 the blade. In this embodiment the stylus is not
3 present. The ultrasonic cutting device is mounted on
4 the mounting table (130) by means of a clamping
5 assembly (140). The clamping assembly includes an
6 upright member (150) that extends from a first end
7 perpendicularly from the mounting table, a support
8 member (160) that extends laterally from the upright
9 member and is held relative to the upright member by
10 a fixing block (170), and a clamp (180) which
11 secures the ultrasonic cutting device to the clamp
12 support member. The clamp support member is
13 slideably moveable up and down a portion of the
14 upright member by turning of an adjusting screw
15 (190). In addition, the clamp support member is
16 slideably moveable laterally in relation to the
17 upright member, this movement being effected by the
18 rotation of a second adjusting screw (200). The
19 clamp support member is located between the fixing
20 block and a securing plate (210). The securing
21 plate can be moved towards the upright member to
22 secure the clamp support member at a suitable
23 position.

24 As shown in figure 16 an arm (220) can extend from
25 the clamp (180) to the cutting blade. A ball
26 bearing (222) is rotatably mounted at one end of the
27 arm and is positioned just above, but not in contact
28 with, the blade. In use the ball bearing is in
29 contact with the surface of the article to be cut
30 and its position controls the extent of blade
31 penetration into the article.

1 Figure 17 shows a perspective view of the cutting
2 apparatus in position for operation without the
3 stylus guide. The heart valve leaflet to be cut is
4 mounted on a 3-axis drive unit (230). This drive
5 unit may be driven by electric motors. Figure 18 is
6 a side view of the embodiment shown in figure 17.

7
8 In the embodiment of Figures 17 and 18, movement of
9 the drive means causes the heart valve leaflet to be
10 cut to be brought into contact with the blade. By
11 accurate positioning of the heart valve leaflet to
12 be cut, the cutting process may be accurately
13 repeated. A set pattern can then be followed and may
14 be instructed by a computer which drives the drive
15 means.

16
17 Leaflets of the geometry described herein can be
18 produced using methods known in the art such as
19 injection moulding, reaction injection moulding,
20 compression moulding or dip moulding.

21
22 In one embodiment the heart valve leaflets may be
23 made by inverted dip moulding. As shown in figure
24 14a an embodiment of inverted dipping apparatus may
25 comprise a platform (1000) holding a forming element
26 (1110). A housing (1130) is sealed to the platform
27 to form a closed chamber (1140). The housing
28 comprises side walls (1150) and a ceiling (1160) and
29 is provided with inlet means (1170) which can be
30 closed by valve (1180).

31

1 The platform is adapted to hold at least one forming
2 element. Preferably the platform is adapted to hold
3 one forming element. By hold means the forming
4 element is secured to the platform so that it will
5 remain in place even upon inversion or rotation of
6 the platform. Preferably the forming element is
7 releasably held on the platform.

8
9 The forming element has a shape so that when coated
10 with the moulding solution it will produce an
11 article of the desired size and shape. The forming
12 element may comprise a core holding a frame which
13 when coated with the moulding solution will produce
14 a leaflet of the desired size and shape.

15
16 In a preferred embodiment, the forming element
17 (1110) is of two-part form, as is shown in Figure
18 14C. The forming element comprises a frame mount
19 (1112) fixed to a base portion (1114). A frame 8,
20 for a heart valve prosthesis, can be mounted on the
21 frame mount 1112. The frame mount is fixed to the
22 base by fixing means for example a screw (1116) or
23 any suitable fixing means such as a bayonet fitting
24 or push fit fitting. The frame mount is removable
25 from the base portion.

26
27 A frame mount and base portion, (two part forming
28 element) may be used during leaflet construction,
29 the frame mount being suitably shaped to a frame to
30 be mounted on the frame mount and allow the
31 production of the leaflets by dip moulding. The
32 frame mount can also be used to hold the frame and

1 leaflets during subsequent cutting of the valve
2 leaflets. The frame mount is releasably attachable
3 to the base forming element portion such that the
4 frame mount portion can be removed from the base
5 portion so that the base portion may be reused. The
6 frame mount portion may be releasably attachable to
7 the base portion by a screw. Should the frame mount
8 be damaged during the cutting stage the frame mount
9 can be discarded while retaining the base portion
10 and thus only a part and not the entire forming
11 element need be replaced. In addition, different
12 types of forming element mounts capable of mounting
13 frames of different diameters or with different
14 valve leaflet shapes can be fixed to the same base
15 portion thus reducing the need for complete forming
16 elements.

17

18 The housing (1140) has an open end (1142) so that
19 when placed on the platform (1000) the forming
20 element can extend into the housing.

21

22 The housing is of a shape and size so that it fits
23 over the forming element (1110) and has the capacity
24 to hold enough moulding solution to coat the forming
25 element. The housing has a ceiling (1160) which is
26 the part of the housing opposite to the platform.
27 The housing may have any suitable shape, for example
28 it may be a cylinder having one closed and one open
29 end, with its closed end being the ceiling.

30

31 Typically the platform and the housing are
32 constructed from steel.

1
2 The apparatus is provided with means for inverting
3 the closed chamber. The inverted and open chamber
4 is shown in figure 14b. Inversion of the housing
5 may be provided by means for rotating the platform
6 about a horizontal axis. In one embodiment, the
7 platform is rotatable about a horizontal axis
8 through the horizontal plane of the platform. This
9 may be achieved by having the platform pivotally
10 supported on a frame. The frame may comprise
11 lateral pins which extend laterally from the frame
12 into the platform so that the platform can rotate
13 around them. In an alternative embodiment, the
14 housing is rotatable about a horizontal axis in the
15 horizontal plane of the open end of the housing.
16 This may be achieved by having the housing pivotally
17 supported on a frame. The frame may comprise
18 lateral pins which extend laterally from the frame
19 into the housing so that the housing can rotate
20 around them.
21
22 Preferably inversion of the closed chamber is
23 effected by drive means including a hand crank and
24 an electric motor.
25
26 The closed chamber has closeable inlet means for
27 introducing the moulding solution to the closed
28 chamber. The inlet means may be closeable by means
29 of a valve. The inlet means are preferably an
30 opening in the ceiling of the housing and are
31 provided with a pipe in connection with a central
32 reservoir of moulding solution. In one embodiment

1 the platform is provided with the inlet means. The
2 inlet means may alternatively be provided in one of
3 the side walls of the housing so that it will be in
4 a position close to the platform in the closed
5 chamber. In this embodiment the moulding solution
6 may be pumped from a reservoir into the closed
7 chamber via the inlet means. This latter embodiment
8 is preferred when more viscous moulding materials
9 are being used.

10

11 Preferably the inlet means and/or the outlet means
12 are heated. The moulding solutions generally used
13 in the moulding of surgical implants are generally
14 viscous in nature and this viscous nature can make
15 the movement of the moulding solutions through the
16 inlet and outlet means difficult to achieve.
17 Heating means can be incorporated in the moulding
18 apparatus and used to heat both the housing and the
19 inlet and outlet means. The raised temperatures of
20 the moulding solutions make these solutions less
21 viscous allowing easier movement of the solutions
22 through inlet and outlet tubes.

23

24 The housing has closeable outlet means. Preferably
25 an opening/pipe in the ceiling of the housing forms
26 the outlet means. When the housing is inverted then
27 the moulding solution can be drained through such an
28 opening/pipe under the force of gravity. The outlet
29 means may be closeable by means of a valve.

30

1 Preferably, as in the embodiment shown in Figures
2 14a and 14b, the outlet means is also the inlet
3 means.

4
5 In operation, a forming element is releasably
6 secured to the platform and a housing is placed over
7 the forming element and sealed to the platform. The
8 closed chamber thus formed should be in a position
9 whereby the forming element is upright. Moulding
10 solution is introduced into the chamber through the
11 inlet means until it reaches a level above the
12 forming element, e.g. level (1152) indicated in
13 Figure 14a. At this stage the inlet means is closed
14 by means of valve (1180). After a suitable period
15 of time, the platform, and thus the closed chamber,
16 is inverted by rotating, in this case, the platform
17 around a horizontal axis. The inverted chamber is
18 then left for a suitable period of time before the
19 housing/platform seal is broken and the housing is
20 lowered. This exposes the now-coated forming
21 element in an inverted position. This can be seen
22 in Figure 14b. The moulding solution can then be
23 drained from the housing using the inlet means
24 (1170) which doubles as outlet means in this
25 embodiment. Alternatively the moulding solution can
26 be drained from the housing before the
27 housing/platform seal is broken. The coating on the
28 forming element can now be dried/cured/treated
29 appropriately.

30

31 As the closed chamber is a sealed system it is
32 possible to exchange the air present in the interior

1 of the closed chamber, when moulding solution is not
2 present, with another solution or gas. The type of
3 solution or gas with which the mould chamber can be
4 filled prior to introduction of moulding solution
5 can be chosen in line with manufacturing
6 requirements. In this way, contact between the
7 mould solution and moisture in the air can be
8 avoided.

9
10 In one embodiment the apparatus comprises a
11 plurality of platforms and a plurality of housings.
12 In this embodiment, preferably all the inlet means
13 are in connection with a central reservoir of
14 moulding solution, with the inlet means and the
15 reservoir forming a manifold. Preferably the
16 manifold is heated. In this embodiment, preferably
17 all the platforms are pivotally supported as a unit
18 on a frame or all the housings are pivotally
19 supported as a unit on a frame. Batch moulding
20 carries the advantages of having greater consistency
21 of results and of being more cost effective.

22
23 As discussed the circumferential length XY of the
24 leaflet at any height point in Z along the post of
25 the frame is explicitly provided by a parabolic
26 function or a pseudo function used to describe a
27 parabolic function. As is clear from figures 1e, 1f
28 and 1g, the manufacture of valve leaflets in the
29 closed position, as described herein, by dip
30 moulding or injection techniques would be difficult
31 as the free edges of the leaflets contact each
32 other. Although a forming element could be provided

1 in which the valve leaflets were produced in the
2 open position, it is more desirable to form the
3 leaflet in a neutral position between the two
4 extremes of fully open or fully closed.

5

6 One method of forming the leaflets is to determine
7 the length of the leaflet in the XY direction for
8 each point in Z for a preferred shape of leaflet.

9

10 On determining the length of the leaflet at each
11 point in Z to minimise the formation of a belly in
12 the leaflet and using appropriate correction factors
13 to determine a final XY length at that point in Z, a
14 wave function can be applied to the leaflet at that
15 point in Z. As shown in figure 12 the wave function
16 will change the shape of the leaflet at that point
17 in Z from a parabolic curve to a desired cast shape,
18 but the length of the leaflet as determined by the
19 initial parabolic shape will be maintained and
20 following manufacture of the valve, closure of the
21 valve, will cause the leaflet to adopt a parabolic
22 shape again at each point in Z.

23

24 The wave shape of the leaflet is used to provide a
25 forming element with leaflet forming surfaces of the
26 shape as defined by the waves arranged in Z for
27 casting of leaflets.

28

29 The valve is thus produced such that in a cast
30 position the leaflet is in neutral position,
31 intermediate the open and closed position in the
32 absence of fluid pressure being applied to the

1 leaflets. Production of the valve in the neutral
2 position means that the leaflets are substantially
3 free of bending stresses in this position.

4

5 The shape of the forming element, on which the
6 leaflet is formed, can be defined by one wave
7 function, or several wave functions which together
8 form a composite wave.

9

10 Regardless of the wave function used for the casting
11 of the leaflet, the length of the leaflet is defined
12 at each point in Z along the post of the scallop by
13 a parabolic function or pseudo parabolic function as
14 described above together with any correction
15 factors.

16

17 The shape of the inner surface of the leaflets will
18 substantially replicate the shape of the forming
19 element. The shape of the outer surface of the
20 leaflets will be similar to the shape of the inner
21 surface, but variations will result e.g. from the
22 properties of the polymer solution and techniques
23 used to create the leaflet.

24

25 The leaflets of suitable length as defined by the
26 parabolic function and any correction factors and of
27 shape as defined by either a single or composite
28 wave function are attached to a suitable frame. The
29 construction of a suitable frame will be obvious to
30 those skilled in the art. The frame can be made of
31 a biocompatible polymer, metal or composite. The

1 frame can be coated with polyurethane to allow
2 integration of the leaflets.

3
4 Further to describing a first leaflet using the
5 above function, the remaining two leaflets of this
6 three leaflet embodiment can be determined by
7 rotating the geometry about the Z axis through 120°
8 and then through 240°.

9
10 Having formed the leaflets of the valve as described
11 above these can then be trimmed to introduce a
12 parabolic curve into the the edge of the leaflet not
13 attached to the frame (free edge) which extends
14 horizontally between two posts. The maximum depth
15 of the parabola being located between 50µm to 1000µm
16 lower than the notional straight line between the
17 ends of the parabola toward the portion of the
18 leaflet which attaches the leaflet to the scallop
19 portion of the frame.

20
21 As shown in figure 13, surprisingly, in addition to
22 reducing the lateral stress of the valve,
23 determination of the length of the leaflet at each
24 point in Z according to a parabolic function not
25 only minimises the formation of a belly in the
26 leaflet, but also reduces the pressure gradient
27 required to open the valve from a closed position.

28
29 The opening of a cardiac valve to as wide an orifice
30 as possible under minimal pressure gradients is a
31 key parameter in the design of synthetic heart
32 valves.

1
2 A valve of the present invention may be used in any
3 required position within the heart to control blood
4 flow in one direction, or to control flow within any
5 type of cardiac assist device.

6
7 Modifications and improvements can be incorporated
8 without departing from the scope of the invention.

9